

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA; THE STATES :
OF CALIFORNIA, COLORADO, CONNECTICUT,
DELAWARE, FLORIDA, GEORGIA, HAWAII, :
ILLINOIS, INDIANA, LOUISIANA, MARYLAND,
MASSACHUSETTS, MICHIGAN, MINNESOTA, :
MONTANA, NEVADA, NEW HAMPSHIRE, NEW
JERSEY, NEW MEXICO, NEW YORK, NORTH :
CAROLINA, OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VIRGINIA, WISCONSIN;
THE DISTRICT OF COLUMBIA; THE CITY OF
CHICAGO, AND THE CITY OF NEW YORK, *EX*
REL., AND OSWALD BILLOTTA,

USDS SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #: _____
DATE FILED: 1/30/15

11 Civ. 0071 (PGG)

**STIPULATED
CONFIDENTIALITY
AGREEMENT AND
PROTECTIVE ORDER**

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

-----x

WHEREAS, all the parties to this action (collectively the "Parties" and individually a "Party") request that this Court issue a protective order pursuant to Federal Rule of Civil Procedure 26(c) to protect the confidentiality of nonpublic and competitively sensitive information that they may need to disclose in connection with discovery in this action;

WHEREAS, the Parties, through counsel, agree to the following terms; and

WHEREAS, this Court finds good cause exists for issuance of an appropriately tailored confidentiality order governing the pretrial phase of this action;

IT IS HEREBY ORDERED that any person subject to this Order—including without limitation the Parties to this action (including their respective corporate parents, successors, and assigns), their representatives, agents, experts and consultants, all third parties

providing discovery in this action, and all other interested persons with actual or constructive notice of this Order—will adhere to the following terms, upon pain of contempt:

1. With respect to “Discovery Material” (*i.e.*, information of any kind produced or disclosed in the course of discovery in this action) that a person has designated as “Confidential” pursuant to this Order, no person subject to this Order may disclose such Confidential Discovery Material to anyone else except as this Order expressly permits.

2. The Party or person producing or disclosing Discovery Material (“Producing Party”) may designate as Confidential only the portion of such material that it reasonably and in good faith believes consists of:

- (a) previously non-disclosed financial information (including without limitation profitability reports or estimates, percentage fees, design fees, royalty rates, minimum guarantee payments, sales reports, and sale margins);
- (b) previously non-disclosed material relating to ownership or control of any non-public company;
- (c) previously non-disclosed business plans, product-development information, clinical research, or marketing plans;
- (d) any information of a personal or intimate nature regarding any individual;
- (e) health care information subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) Privacy Rule, 45 C.F.R. pts. 160 and 164, and/or other applicable state or federal law or regulation concerning confidential health information; or
- (f) any other category of information this Court subsequently affords confidential status.

3. With respect to the Confidential portion of any Discovery Material other than deposition transcripts and exhibits, the Producing Party or its counsel may designate such portion as “Confidential” by stamping or otherwise clearly marking as “Confidential” the protected portion in a manner that will not interfere with legibility or audibility. Upon request by the

Receiving Party, the Producing Party will produce for future public use another copy of said Discovery Material with the confidential information redacted. A Producing Party may designate any magnetic or electronic media (e.g., videotape or computer disk or DVD/CD Rom disk) as Confidential Information by placing or affixing a label on such media marking it as "Confidential." Wherever practicable, Confidential Information produced electronically shall be formatted such that printed copies of any document(s) contained therein shall print with a header or footer stating, "CONFIDENTIAL INFORMATION — Subject to Protective Order."

Information to be treated as "Confidential" under this order includes all materials labeled as "Confidential" that have been produced to the United States Attorney's Office for the Southern District of New York in response to any Civil Investigative Demands or subpoenas in connection with the investigation underlying this action.

4. A Producing Party or its counsel may designate deposition exhibits or portions of deposition transcripts as Confidential Discovery Material either by: (a) indicating on the record during the deposition that a question calls for Confidential information, in which case the reporter will bind the transcript of the designated testimony in a separate volume and mark it as "Confidential Information Governed by Protective Order;" or (b) notifying the reporter and all counsel of record, in writing, within 30 days after a deposition has concluded, of the specific pages and lines of the transcript that are to be designated "Confidential," in which case all counsel receiving the transcript will be responsible for marking the copies of the designated transcript in their possession or under their control as directed by the Producing Party or that person's counsel. During the 30-day period following a deposition, all Parties will treat the entire deposition transcript as if it had been designated Confidential.

5. If at any time before the trial of this action a Producing Party realizes that it should have designated as Confidential some portion(s) of Discovery Material that it previously produced without limitation, the Producing Party may so designate such material by so apprising all prior recipients in writing. Thereafter, this Court and all persons subject to this Order will treat such designated portion(s) of the Discovery Material as Confidential.

6. Nothing contained in this Order will be construed as: (a) a waiver by a Party or person of its right to object to any discovery request; (b) a waiver of any privilege or protection; or (c) a ruling regarding the admissibility at trial of any document, testimony, or other evidence.

7. Where a Producing Party has designated Discovery Material as Confidential, other persons subject to this Order may disclose such information only to the following persons:

- (a) the Parties to this action, their insurers, and counsel to their insurers;
- (b) counsel retained specifically for this action, including any paralegal, clerical, or other assistant that such outside counsel employs and assigns to this matter, as well as any external auditors or vendors that outside counsel retains to provide litigation support services;
- (c) outside vendors or service providers (such as copy-service providers and document-management consultants) that counsel hire and assign to this matter;
- (d) any mediator or arbitrator that the Parties engage in this matter or that this Court appoints, provided such person has first executed a Non-Disclosure Agreement in the form annexed as an Exhibit hereto;
- (e) as to any document, its author, its addressee, and any other person indicated on the face of the document as having received a copy;
- (f) any witness who counsel for a Party in good faith believes may be called to testify at trial or deposition in this action, provided that any such witness not retain any copies of Discovery Material designated as Confidential;
- (g) any person a Party retains to serve as an expert witness or otherwise provide specialized advice to counsel in connection with this action, provided such person has first executed a Non-Disclosure Agreement in the form annexed as an Exhibit hereto;

- (h) stenographers engaged to transcribe depositions the Parties conduct in this action; and
- (i) this Court, including any appellate court, its support personnel, and court reporters.

8. Before disclosing any Confidential Discovery Material to any person referred to in subparagraphs 7(d) or 7(g) above, counsel must provide a copy of this Order to such person, who must sign a Non-Disclosure Agreement in the form annexed as an Exhibit hereto stating that he or she has read this Order and agrees to be bound by its terms. Said counsel must retain each signed Non-Disclosure Agreement, hold it in escrow, and produce it to opposing counsel upon request.

9. In accordance with paragraph 2 of this Court's Individual Practices, any party filing documents under seal must simultaneously file with the Court a letter brief and supporting declaration justifying – on a particularized basis – the continued sealing of such documents. The parties should be aware that the Court will unseal documents if it is unable to make “specific, on the record findings . . . demonstrating that closure is essential to preserve higher values and is narrowly tailored to serve that interest.” Lugosch v. Pyramid Co. of Onondaga, 435 F.3d 110, 120 (2d Cir. 2006).

10. The Court also retains discretion whether to afford confidential treatment to any Discovery Material designated as Confidential and submitted to the Court in connection with any motion, application, or proceeding that may result in an order and/or decision by the Court. All persons are hereby placed on notice that the Court is unlikely to seal or otherwise afford confidential treatment to any Discovery Material introduced in evidence at trial, even if such material has previously been sealed or designated as Confidential.

11. In filing Confidential Discovery Material with this Court, or filing portions of any pleadings, motions, or other papers that disclose such Confidential Discovery Material

(“Confidential Court Submission”), the Parties shall publicly file a redacted copy of the Confidential Court Submission via the Electronic Case Filing System. The Parties shall file an unredacted copy of the Confidential Court Submission under seal with the Clerk of this Court, and the Parties shall serve this Court and opposing counsel with unredacted courtesy copies of the Confidential Court Submission.

12. Any Party who objects to any designation of confidentiality may at any time before the trial of this action serve upon counsel for the Producing Party a written notice stating with particularity the grounds of the objection. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 4(E) of this Court’s Individual Practices.

13. Any Party who requests additional limits on disclosure (such as “attorneys’ eyes only” in extraordinary circumstances), may at any time before the trial of this action serve upon counsel for the recipient Parties a written notice stating with particularity the grounds of the request. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 4(E) of this Court’s Individual Practices.

14. Recipients of Confidential Discovery Material under this Order may use such material solely for the prosecution and defense of this action and any appeals thereto, and not for any business, commercial, or competitive purpose or in any other litigation proceeding. Nothing contained in this Order, however, will affect or restrict the rights of any Party with respect to its own documents or information produced in this action.

15. Nothing in this Order will prevent any Party from producing any Confidential Discovery Material in its possession in response to a lawful subpoena or other compulsory

process, or if required to produce by law or by any government agency having jurisdiction, provided that such Party gives written notice to the Producing Party as soon as reasonably possible, and if permitted by the time allowed under the request, at least 10 days before any disclosure. Upon receiving such notice, the Producing Party will bear the burden to oppose compliance with the subpoena, other compulsory process, or other legal notice if the Producing Party deems it appropriate to do so.

16. Nothing in this Order will prevent or in any way limit the right or duty of the United States or the State of New York to disclose to any agency or department of the United States or the State of New York, or any division of any such agency or department, any Confidential Discovery Material relating to a potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order prevent or in any way limit the use of any such Confidential Discovery Material by any such agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction.

17. Nothing in this Order will prevent or in any way limit the right or duty of the United States or the State of New York to provide any Confidential Discovery Material to the United States Congress pursuant to a congressional request; provided, however, that the United States or the State of New York shall notify the congressional entity requesting the Confidential Discovery Material that the Confidential Discovery Material was produced pursuant to this Order and the United States or the State of New York will, if there are no objections interposed by the congressional entity requesting the Confidential Discovery Material, use reasonable efforts to notify the Producing Party of the congressional entity's request and the United States' or the

State of New York's response thereto in advance of providing the Confidential Discovery Material.

18. Each person who has access to Discovery Material designated as Confidential pursuant to this Order must take all due precautions to prevent the unauthorized or inadvertent disclosure of such material.

19. In the event of a disclosure of any Confidential Discovery Material to a person not authorized to have had such disclosure made to him or her under this Order, and in the event the party responsible for having made or allowed such disclosure becomes aware of such disclosure, that party shall immediately inform counsel for the Producing Party whose Confidential Discovery Material has thus been disclosed of all relevant information concerning the nature and circumstances of such disclosure. The responsible party also shall take all reasonable measures promptly to ensure that there is no further or greater unauthorized disclosure of the Confidential Discovery Material.

20. If a Producing Party inadvertently produces documents containing privileged information (i.e., any information that may properly be withheld from discovery pursuant to Federal Rule of Civil Procedure 26(b)(5) on the grounds of attorney client privilege, deliberative process privilege, law enforcement privilege, work product protection, or other applicable privileges or immunities), such party's inadvertent production of any such documents will not constitute a waiver of privilege. Upon receiving notice from the Producing Party or its counsel that a particular document or class of documents has been inadvertently produced and is claimed to be privileged, or to contain privileged information, the parties in receipt of the inadvertently produced document(s) will promptly take reasonable steps to locate and return or destroy all copies of any such documents. Any such documents shall not thereafter be used by the parties in

receipt of the documents for any purpose, unless and until the documents are adjudicated to be non-privileged. Nothing in this paragraph shall alter an attorney's responsibilities under applicable law or codes of ethics when confronted with inadvertently produced privileged information.

21. Within 60 days of the final disposition of this action—including all appeals—all recipients of Confidential Discovery Material must either return it—including all copies thereof—to the Producing Party, or, upon permission of the Producing Party, destroy such material—including all copies thereof. In either event, by the 60-day deadline, the recipient must certify its return or destruction by submitting a written certification to the Producing Party that affirms that it has not retained any copies, abstracts, compilations, summaries, or other forms of reproducing or capturing any of the Confidential Discovery Material. Notwithstanding this provision, the attorneys that the Parties have specifically retained for this action may retain an archival copy of all pleadings, motion papers, transcripts, expert reports, legal memoranda, correspondence, or attorney work product, even if such materials contain Confidential Discovery Material. Any such archival copies that contain or constitute Confidential Discovery Material remain subject to this Order.

22. This Order will survive the termination of the litigation and will continue to be binding upon all persons to whom Confidential Discovery Material is produced or disclosed.

23. This Court will retain jurisdiction over all persons subject to this Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt thereof.

SO STIPULATED AND AGREED.

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Southern District of New York

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DATED: 5, 2014
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*Attorneys for Defendant Novartis
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SO ORDERED.

HON. PAUL GARDEPHE
UNITED STATES DISTRICT JUDGE

PREET BHARARA
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SO ORDERED.

HON. PAUL GARDEPHE
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*Attorneys for Defendant Novartis
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SO ORDERED.

Paul J. Gardephe
HON. PAUL GARDEPHE
UNITED STATES DISTRICT JUDGE

EXHIBIT A

**UNITED STATES DISTRICT COURT
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UNITED STATES OF AMERICA; THE STATES :
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REL., AND OSWALD BILOTTA,

**NON-DISCLOSURE
AGREEMENT**

Plaintiffs,

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NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

-----x

I, _____, acknowledge that I have read and understand the Protective Order in this action governing the non-disclosure of those portions of Discovery Material that have been designated as Confidential. I agree that I will not disclose such Confidential Discovery Material to anyone other than for purposes of this litigation and that at the conclusion of the litigation I will return all discovery information to the Party or attorney from whom I received it. By acknowledging these obligations under the Protective Order, I understand that I am submitting myself to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any issue or dispute arising hereunder and that my willful violation of any term of the Protective Order could subject me to punishment for contempt of Court.

Date: _____

[Signature]